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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DOUGHERTY, SEAN PATRICK

ART UNIT

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3736

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/424,440	Applicant(s) HURTAK ET AL.	
	Examiner SEAN P. DOUGHERTY	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/08/2000, 02/26/2001, 02/13/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This is the *initial* Office action based on the 09/424440 application filed November 23, 1999. Claims 1-12, as originally filed, are currently pending and have been considered below. Claim 1 is independent.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

United States Patents Box et al (4,846,186) and Corso, Jr. et al (5,259,393) are not in a proper information disclosure statement

Claim Objections

Claims 1-12 are objected to because of the following informalities:

Claim 1 recites the limitation "the length of the guidewire" in line 5 and "the flexibility and torsion characteristics" in line 9;

Claim 2 recites the limitation "the length of the metal distal tip" in lines 15-16 and "the wavelength of a magnetic resonance field" in lines 16-17;

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Claim 5 recites the limitation “the material” in line 1;

Claim 6 recites the limitation “the material” in line 5;

Claim 7 recites the limitation “the material” in line 8 and “the metal distal tip” in lines 8-9;

Claim 8 recites the limitation “the diameter of a major portion” in lines 12-13;

Claim 10 recites the limitation “the transition point” in line 21;

Claim 11 recites the limitation “the material” in line 1; and

Claim 12 recites the limitation “the selective steering” in line 5.

There is insufficient antecedent basis for these limitations in these claims above.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne (US Patent No. 5,251,640: cited in IDS) in view of Weber (US Patent No. 5,728,079).

1. Osborne discloses a medical guidewire for use in intravascular medical procedures and compatible with magnetic resonance, the guidewire having proximal and distal ends, comprising:

a relatively long, thin core extending for substantially the length of the guidewire, the core being made of a glass having a high specific electric impedance (fiber layer [72]);

a polymer sheath surrounding the core (polyethylene sleeve [74]); and
a plurality of reinforcing fibers affixed to at least one of the core and the polymer sheath, to enhance the flexibility and torsion characteristics of the guidewire (fiber layer [73]).

Osborne does not appear to disclose wherein:

at least one marker positioned near a distal end of the guidewire, wherein the marker is visible under magnetic resonance due to susceptibility-induced magnetic field inhomogeneity.

However, Weber discloses a reference in analogous art wherein:

at least one marker positioned near a distal end of the guidewire, wherein the marker is visible under magnetic resonance due to susceptibility-induced magnetic field inhomogeneity (col. 3, lines 17-34; see abstract).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Osborn and Weber before him or her to include the marker of Weber with the guidewire shaft of Osborn. The motivation for doing so would have been "to provide an improved composite wire guide shaft" (Osborne: col. 1, lines 58-59) and to provide a marker with " enough paramagnetic substance to render at least a predetermined portion of the catheter visible during magnetic resonance imaging of body tissue" (Weber: see abstract).

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2. Osborne discloses the medical guidewire of Claim 1, further comprising:

a relatively short distal tip segment made of metal components affixed to the glass core at a transition point, wherein the length of the metal distal tip segment is substantially shorter than the wavelength of a magnetic resonance field (nitinol central core [71]).

3. Osborne discloses the magnetic guidewire of Claim 1, wherein:

the reinforcing fibers are affixed to the core (fiber lay [73] is affixed to fiber layer [72] as seen in Fig. 8).

4. Osborne discloses the magnetic guidewire of Claim 1, wherein:

the reinforcing fibers are affixed to the polymer sheath (fiber layer [73] is affixed to polyethylene sleeve [74] as seen in Fig. 9).

5. Osborne discloses the magnetic guidewire of Claim 4, wherein:

the material of the reinforcing fibers is selected from the group consisting of carbon, borium, aramide, and glass (col. 4, lines 7-11).

6. Osborne discloses the magnetic guidewire of Claim 1, wherein:

the material of the core is selected from the group consisting of fiberglass, silica, and quartz (col. 4, lines 7-11).

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7. Osborne discloses the magnetic guidewire of Claim 2, wherein:
the material of the metal distal tip segment is nitinol (nitinol central core [71]).
8. Osborne discloses the magnetic guidewire of Claim 1, wherein:
a distal segment of the glass core tapers to a diameter at the distal end of the guidewire that is smaller than the diameter of a major portion of the core (col. 3, lines 15-21; see Fig. 2 through Fig. 5).
9. Osborne discloses the magnetic guidewire of Claim 2, wherein:
the polymer sheath extends continuously from a location near the proximal end of the guidewire, to a location distal of the transition point, thus surrounding at least a portion of both the glass core and the metal distal tip segment (polyethylene sleeve [74] extends over the nitinol central core [71], fiber layer [72], and fiber lay [73] as seen in Fig. 8; col. 5, lines 40-41; see abstract).
10. Osborne discloses the magnetic guidewire of Claim 1, further comprising:
a short metal collar affixed to the guidewire at the transition point, to resist kinking and breakage of the guidewire at the transition point (nitinol central core [71]; col. 5, lines 45-48).
11. Weber discloses the magnetic guidewire of Claim 1, wherein:
the material of the marker is Dysprosium Oxide or Dy_2O_3 (col. 3, line 31).

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12. Osborne discloses the magnetic guidewire of Claim 1, wherein:

the distal tip of the guidewire is bent slightly, to facilitate the selective steering of the guidewire along a desired vascular path. Osborne establishes a distal end of the guidewire is capable of bending slightly when pressure is applied (col. 5, lines 45-48).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Thursday, 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. P. D./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736